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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,331	02/08/2001	Gregory E. Agoston	43170-253406 (05213-0731)	5897

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,331

Applicant(s)

AGOSTON ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9 and 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9 and 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 10 & 13.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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This application is a division of 09/641,327. Applicant's response filed in paper no. 11 and 12 is hereby acknowledged. Amendments are entered. Claims 1-9 and 11-22 are pending. No claim is allowed. Instant invention is drawn to 2-substituted estradiols of claim 1 and 11.

Claim Rejections - 35 USC § 103

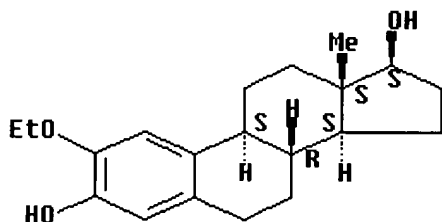
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patent ability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

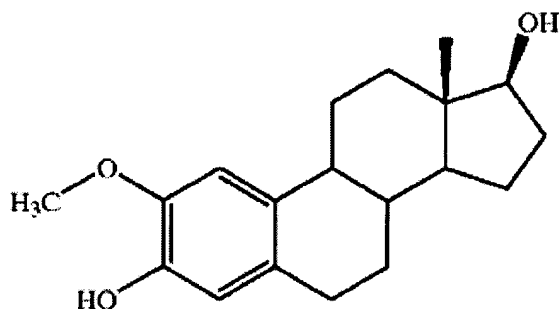
Claims 1-9 and 11-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al. (US Patent 6,054,598). See compound no 10 in scheme which is 2-ethoxy estradiol (see also example 6B in col. 13), following is the structure of 2-ethoxyestradiol.



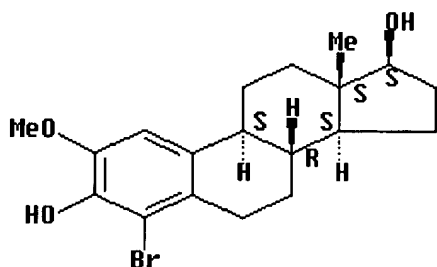
Claims 1-9 and 11-22 rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato et al. (US Patent 5,504,074). 2-methoxy estradiol compound no. 1, (see table 1 in cols. 15 and 16), see when

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in instant claims when Ra is O-R (R is ethyl); Rg is C (H)-OH; Ro and Rb is H; Z' is OH; Z'' is CH₂. See 1st two compounds in Table 2, col.; Table 1 see line 32, 37, 38, 41, in col. 8. Following is the structure of 2-methoxyestradiol.

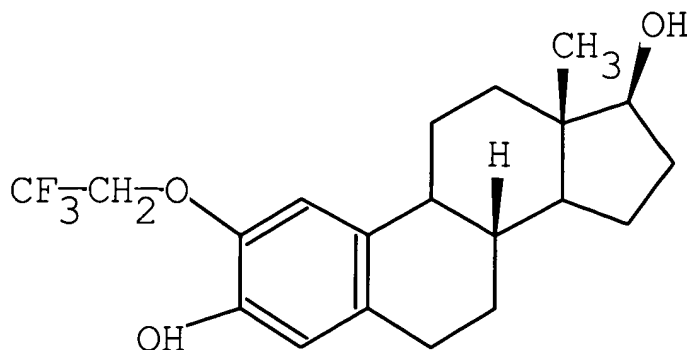


Claims 1-9 and 11-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Pert et al. (DN 111:233338, CAPLUS, abstract of Australian J. of Chem. (1989), 42(3), 421-32). See the following compound, which is 4-bromo-2methoxyestradiol, and compound I in the abstract.



Claims 1-9 and 11-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Ram et al. (US Patent 6,136,992), See compound (3) in Fig. 1 and compound of claim 2, when Rh1, Rh2, Rb and R0 is H; Z' is >COH; Z'' is >CH₂; >C-Rg is >COH and Ra is OR-R1, R is CH₂ and R1 is CF₃. This trifluoroethoxy estradiol derivative is presented by the following structure.

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Claims 1-9 and 11-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al. (6,051,726). See claims 1 and 2 where 2-alkoxy estradiol are claimed.

All the references cited above differ from the reference in having no substituent at 16-position whereas presently claimed compounds can have one methyl group, ethyl group or an alkyl group (see proviso in claim when both Rh1 or Rh2 cannot be hydrogen, when one is H, other is Me). Even though the compounds as cited above are disclaimed however, the difference i.e. H v. Me is considered obvious. Compounds that differ only by the presence of an extra methyl group are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue.

The prior art of record is drawn to structurally similar compounds, which differ, from the compounds embraced by the instant claims in that they are homologs. The skilled artisan would have been motivated to modify the teaching of the prior art to prepare homologs because it is recognized in the art that homologs are structurally similar and would be expected to possess similar properties. *Ex parte Henze* (POBA 1948) 83 USPQ 167.

The homologue is expected to be prepared by the same method and to have the same properties. This expectation is then deemed the motivation for preparing homologues. The homologues are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39.

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In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

December 1, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER